



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/090,798 | 03/06/2002 | Amanda S. Schilling | 83202 | 6616 |

7590 09/09/2003

James B. Bechtel, Esq.
NSWCDD (XDC1)
Dahlgren, VA 22448-5100

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/090,798 | SCHILLING ET AL. |
| | Examiner Dr. Kailash C. Srivastava | Art Unit 1651 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 17 June, 2003 as Paper Number 5.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-19 and 21 is/are pending in the application.

4a) Of the above claim(s) 17-19 and 21 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-16 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Applicants' response and amendment filed June 17, 2003 as Paper Number 5 to Office Action mailed May 19, 2003 as paper number 4 is acknowledged and entered.
2. Examiner would like to correct the inadvertent typography in above-cited Office Action in communicating the classification for Group I. The correct statement should read as follows:
 - Group I, consisting of claims 1-16 drawn to a method to decontaminate a composition contaminated with biological spores, classified under Class 424, subclass 602 or 613, for example.

Restriction/Election

3. Applicant's election with traverse of Group I, Claims 1-16 filed June 17, 2003 as Paper Number 5 to election requirement in Office Action mailed May 19, 2003 as paper number 4 is acknowledged and entered. Applicants' traversal is on the grounds that as amended, Claims 17-19 and 21 read on the same composition as claimed in Claim 16 or the claims encompassing invention in Group I. Applicant's arguments have been carefully considered, but are not found persuasive because of the reasons of record on pages 2-3 in Office Action mailed May 19, 2003 as paper number 4 and for the reasons discussed below.

A Restriction requirement is made between inventions encompassing certain claims, not between claims. As amended, invention encompassed in Claims 1-16, Claims 17-18 and 19-21 are still distinct inventions from each other because invention in Group I, encompassing Claims 1-16 is drawn to a method, while inventions in Claims 17-18 and 19, 21 are each drawn to a composition. Invention claimed in claims 17-18 encompassed as Group II is distinct from the invention claimed in Group III because the functional effect of each one of those inventions is different than that of the other, namely, ingredients comprising composition of the invention in Group II are completely different than those encompassed in Invention III. In addition, the search for each of the distinct inventions of Groups I-III is not co-extensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the condition for patentability is different in each case. Thus, it will be an undue burden to examine all of the inventive Groups in one application. Therefore, the restriction requirement is still deemed proper and is made FINAL.

Accordingly, Claims 17-19 and 21 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims cited above be canceled in response to this Office action to expedite prosecution.

4. Claims 1-16 are examined on merits.

Claim Rejections - 35 U.S.C. § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claim 2 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The phrase "step of contacting the contamination with the spore germination composition effective to cause germination of the spore simultaneously with" renders Claim 2 unclear and indefinite. As presented, Claim 2 seems to be incomplete. Applicants should clearly define each of the steps of the method claimed in Claim 2. Examiner Suggests to insert the phrase "is performed" after the word "spores" in line 2.

Claim Rejections - 35 U.S.C. § 103

7. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

9. Claims 1-16 are rejected under 35 U.S.C. § 103 (a) as obvious over Tautvydas (U. S. Patent 5,795,730) in view of Baker, et al. (U. S. Patent 6,506,803) and Slieman et al. (Applied and Environmental Microbiology, 2001, Vol. 67, Pages 1274-1279).

Tautvydas teaches the general concept of simultaneously contacting a contamination containing biological spores in a spore germination medium and exposing said composition to a sterilizant so that the spore containing contaminated solution is decontaminated because vegetative cells emerging through spore germination are sterilized (i.e., killed) by the sterilizant. In said method, *Bacillus subtilis* spores (i.e., a strip mounted with a pre-measured quantity of *Bacillus subtilis* spores) contained in a vial with a spore germination medium are exposed to ethylene oxide (i.e., sterilizant, See Column 3, Lines 27-45) and subsequently spore germination rates are spectrophotometrically determined (See Examples 1-2) against a control. Tautvydas' spore germination (SG) medium comprises peroxygen compounds, calcium chloride and other chloride ions but does not contain an enzyme, a surfactant or dipicolinic acid (Column 15, Lines 20-45 and Column 2, Line 48 where H₂O₂ is present as an sterilizant).

Baker et al. teach a method and a composition to inactivate/decontaminate bacterial cells and spores by exposing them to an oil-in-water emulsion comprising water, a surfactant, an oil, an enzyme and a buffer (Abstract, Lines 1-7; Column 5, Lines 12-15; Column 12, Lines 7-64; Column 18, Lines 18-29; Column 21, Lines 1-32; Column 22, Lines 27-40).

None of the prior art methods cited above teach a composition comprising dipicolinic acid and calcium ions / calcium dipicolanate or calcium chelated with dipicolinic acid to inactivate bacterial spores or decontaminate a solution containing *Bacillus* spores.

Slieman et al. teach that *Bacillus subtilis* spores were germinated when suspended in a freshly prepared solution comprising 60 mM DPA (i.e., dipicolinic acid) and 60 mM CaCl₂ at a pH of 8.0 (Page 1275, Column 2, Lines 12-24). In their method to sterilize said contaminants (i.e., *Bacillus subtilis* spores), Slieman et al. further teach that said spores germinated in solution containing DPA-CaCl₂ were more sensitive to all wavelengths of UV radiation (Abstract, Lines 13-14). Thus, Slieman et al. already teach the inventive concept of sequential or simultaneous sterilization of bacterial spores by germinating them in a solution containing dipicolinic acid and CaCl₂ and a sterilizant, i.e., UV radiation.

One having ordinary skill in the art would have been motivated to modify Tautvydas' teachings according to the teachings from Baker et al. and Slieman et al. to incorporate a surfactant, an enzyme and a solution of dipicolinic acid to Tautvydas' germination medium (SG medium), because all the three prior art methods teach a sterilization/ decontamination method to sterilize/ decontaminate a solution/ material contaminated with bacterial (i.e., *Bacillus* sp.) spores, wherein each one of the prior art reference is essentially substituting one spore germination method for the other and the three germination methods are functional equivalents to reach other with Slieman et al's method having the advantage of incorporating dipicolinic acid and calcium chloride or calcium dipicolonate in their germination method. While all the three prior art references teach the basic inventive concept to apply a germination solution/medium to simultaneously/sequentially germinate bacterial spores and subsequently kill the vegetative cells resulting from germination of spores, Baker et al. remove the deficiency in Tautvydas' spore germination (SG) medium by teaching addition of an enzyme and a surfactant and Slieman et al. remove the deficiency of combining CaCl_2 with dipicolinic acid in methods and compositions from Tautvydas and Baker et al. to germinate the spores and subsequently sterilize the contaminated material with a sterilizant (i.e., UV radiation).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Tautvydas and Baker et al. according to the teachings from Slieman et al. to subject bacterial spores to a germination medium comprised of an enzyme, a surfactant, and a mixture of CaCl_2 and dipicolinic acid along with subsequent or simultaneous exposure to a sterilizant to decontaminate/ sterilize a contaminated material. Thus, Baker et al. remedy the deficiencies in Tautvydas' teachings and Slieman et al. remedy deficiencies in the teachings from both Tautvydas and Baker et al.

None of the above discussed prior art references teach the exact concentrations or weight ratios for different components (e.g., dipicolinic acid or CaCl_2) as claimed in the instant invention. However, adjustment of particular conventional working conditions (e.g., the quantities of each one of components in a given composition, or method of application of a given composition) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter, which is well within the purview of the skilled artisan.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

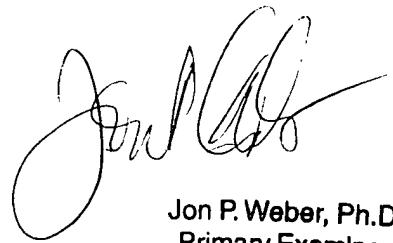
10. No Claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Daylight Saving, or Standard time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9306.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(703)-605-1196
September 8, 2003



Jon P. Weber, Ph.D.
Primary Examiner